4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2015-C-1154]

Listing of Color Additives Exempt from Certification; Mica-Based Pearlescent Pigments;

Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of November 2, 2015, for the final rule that appeared in the <u>Federal Register</u> of September 30, 2015, and that amended the color additive regulations to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as a color additive in certain distilled spirits.

DATES: Effective date of final rule published in the <u>Federal Register</u> of September 30, 2015 (80 FR 58600), confirmed: November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Salome Bhagan, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-3041.

SUPPLEMENTARY INFORMATION: In the <u>Federal Register</u> of September 30, 2015 (80 FR 58600), we amended the color additive regulations in § 73.350 Mica-based pearlescent pigments (21 CFR 73.350) to increase the maximum permitted alcohol content of distilled spirits to which mica-based pearlescent pigments may be added from 23 percent to 25 percent alcohol by

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volume, and to remove the current limitation for distilled spirits mixtures containing more than 5

percent wine on a proof gallon basis.

We gave interested persons until October 30, 2015, to file objections or requests for a

hearing. We received no objections or requests for a hearing on the final rule. Therefore, we

find that the effective date of the final rule that published in the Federal Register of September

30, 2015, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342,

343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the

Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and

Applied Nutrition, we are giving notice that no objections or requests for a hearing were filed in

response to the September 30, 2015, final rule. Accordingly, the amendments issued thereby

became effective November 2, 2015.

Dated: December 4, 2015.

Susan Bernard,

Director.

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

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